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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,830	08/05/2004	Stanley Charles Antosh	41260.004	4829

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/710,830	ANTOSH ET AL.	
	Examiner	Art Unit	
	Joseph S. Kudla	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *18-19,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 20-28* is/are rejected.

7)☒ Claim(s) *1-17 and 20-28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Priority

1. This application is a continuation-in-part of US Non-provisional Application No. 10/710,710, filed July 29, 2004, for which benefit is claimed. Priority is acknowledged.

2. It is noted that this application appears to claim subject matter disclosed in prior Application No. 10/710,710, filed July 29, 2004. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference

required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Election/Restrictions

3. Applicant's election with traverse in the reply filed on November 30, 2007 is acknowledged. The traversal is on the ground(s) that the inventions are not patently distinct and that fat loss, and protein concentration within the body are inextricably linked. Applicant's representative further states that when body fat percentage is reduced, then muscle concentration increases. Applicants' argument is not found persuasive because the searches for the invention involve divergent subject matter (e.g., a search for the mechanism of action for fat loss and a search for the mechanism of action for muscle formation) and would require separate considerations.

The requirement is still deemed proper and is therefore made FINAL.

4. Applicant's November 30, 2007 correspondence elects Group I, which encompasses claims 1-17 and 20-28. The invention contained in Group II, encompassing claims 18-19 and 29-30 is withdrawn from consideration, as being drawn to non-elected subject matter. See 37 CFR 1.142(b). Accordingly, the subject matter now under consideration is drawn to claims 1-17 and 20-28.

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a

separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specifically, for the references on pages 1-18 in the instant specification to be considered on the merits, the references must be cited on a PTO/SB/08 and a copy of the reference provided, unless the reference is a US Patent or a published US Patent Application.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

6. The Specification as set forth is not in the proper format. Specification headings should appear in upper case, without underlining or bold type. Some section headings are missing (e.g., Cross-References to Related Applications, Statement Regarding Federally Sponsored Research and Development and The Names of the Parties to a Joint Research Agreement). If a section heading from the above listed guidance is present and no text follows the section heading, the phrase "Not Applicable" should follow the section heading. Additionally, under Background of Invention, the information on class, field of search, and references cited should be removed.

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract

on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

7. The abstract of the disclosure is objected to because the length (190 words) of the narrative describing the invention is too long in length to fit within the space requirements for printing. Correction is required. See MPEP § 608.01(b).

Title

8. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: REDUCING WEIGHT GAIN IN A MAMMAL WITH METHYL PYRUVATE.

Claim Objections

9. Claims 11 and 22 are objected for the following informalities: The fourth and the fifth lines of both claims have the conjunction word “and" separated by the words “metabolic compounds”. The Examiner believes the phrase is meant to read "metabolic compounds and antioxidants."

10. Applicant is advised that should claims 1, 3, 5 and 10-17 be found allowable, claims 2, 4, 6 and 21-28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 1, 3, 5 and 10-17 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 2, 4, 6 and 21-28. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Appropriate Action is Required.

Claim Rejections - 35 USC § 101 and 112 2nd paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 provide for the use of methyl pyruvate or methyl pyruvic acid, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 20-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claims 1-2 recite the limitation "the use" in the second line of all mentioned claims.

There is no recitation of an active step. Accordingly, the claims lack clarity.

14. Claims 5 and 6 recite the limitation "a therapeutic and effective amount" in the claims.

There is insufficient antecedent basis for this limitation in the claim.

15. Claims 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether or not the parenthetical subject matter around the phrase "such as sodium or potassium methyl pyruvate" in instant claim 7 and "such as calcium and magnesium methyl pyruvate" in instant claim 8 are intended to be claim limitations. The presence of parenthesis leaves the Examiner to question the meaning of the invention Applicant claims, thereby rendering the subject matter of the instant claim unclear.

16. Claims 7-8, 17-18 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "such as sodium or potassium methyl pyruvate" in instant claim 7, "such as calcium and magnesium methyl pyruvate" in instant claim 8 and "preferably" in claims 17-18 and 27-28 render the claims unclear. The phrases "such as" and

"preferably" are open-ended phrases that leave the Examiner to question whether or not claim limitations are intended. The metes and bounds of the instant subject matter are unclear.

17. Claims 6-8, 10-11 and 16-17 recite the limitation "the salt" or "the salts" in the claims.

There is insufficient antecedent basis for this limitation in the claim.

18. Claims 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "can act" in instant claim 9 renders the claim indefinite and hypothetical. The phrase "can act" is an open-ended phrase that leaves the Examiner to question whether Applicant is in possession of the invention for which he is claiming.

Clarification is required.

19. Claims 10-11 and 21-22 recite the limitation "composition" in the claims.

There is insufficient antecedent basis for this limitation in the claim.

20. Claims 12-15 and 23-28 recite the limitation "the form" or "the unit dosage form" in the first line of all mentioned claims.

There is insufficient antecedent basis for this limitation in the claim.

21. Claims 1-17 and 20-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The indication of the group or subject to be treated and the indication for which treatment is given is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the claim. As an example, Claim 1 could be remedied by the addition of a subject or group to which the methyl pyruvate is administered, along with a statement that the therapy is given to increase energy production.

22. Claims 16-17 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language ""preferably about between .5 gram and 5 grams" in instant claims 16-17 and 27-28 and "about 100 mg to about 28 grams" in instant claims 27-28 is indefinite. The assumption is that "between about" or "about' as it is used in the instant claim language represents an open-ended range. Conceivably, the range extends beyond the amounts disclosed, which is an indefinite amount, and leaves the Examiner to question the metes and bounds of the invention Applicant claims. The subject matter of the instant claims is unclear.

Appropriate action is required.

Claim Rejections - 35 USC § 112 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

23. Claims 9 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

Applicant claims "analogs" and "substrate analogs." Because the instant specification does not provide written description of what structures are contemplated for such "analogs" and "substrate analogs," the phrases lack adequate written description.

Regarding the requirement for adequate written description of chemical entities, Applicants' attention is directed to MPEP § 2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F. 3d 1559, 1568 (Fed. Cir. 1997), *cert denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish list or plan for obtaining the claimed chemical invention." Eli Lilly, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the

U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F. 3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant has failed to provide any structural characteristics, chemical formula, name(s) or physical properties of the "analogs" or "substrate analogs" in the instant specification, aside from the broad recitation in instant claims 9 and 20. Structural orientation of functional analogs of methyl pyruvic acid and methyl pyruvate will influence their pharmacological activity. Applicant has failed to disclose specific analogs contemplated for use in the invention. As such, it is not apparent that Applicant was actually in possession of, and intended to use within the context of the present invention, methyl pyruvate or methyl pyruvic acid analogs, at the time the present invention was made.

Appropriate action is required.

24. Claims 1-17 and 20-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an Enablement rejection.

The specification does not reasonably provide enablement for a method of controlling the weight or to induce a weight loss or to reduce and expected weight gain or reduce body fat deposition in a mammal with use of any form of methyl pyruvate or methyl pyruvic acid, *nor* does the specification provide results or evidence of the effects of administering these compounds, *nor* does the specification reasonably provide for administration of a drug composition, *nor* does the specification reasonably provide for the administration of a second compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims without undue experimentation to control the weight or to induce a weight loss or to reduce and expected weight gain or reduce body fat deposition in a mammal with use of any form of methyl pyruvate or methyl pyruvic acid, as set forth in the claims.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)*. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one

skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:
(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims is very broad with relation to the ability of any monovalent or divalent or substrate form of methyl pyruvate or methyl pyruvic acid, with or without a second compound, to control the weight or to induce a weight loss or to reduce and expected weight gain or reduce body fat deposition in a mammal with use of any form of methyl pyruvate or methyl pyruvic acid. The breadth of the instant claims is narrow with relation to the ability of administering the compounds orally or by infusion. Applicant has not provided sufficient evidence or mechanisms of action to support claims drawn to the administration via any means of any monovalent or divalent or substrate form of methyl pyruvate or methyl pyruvic acid to control the weight or to induce a weight loss or to reduce and expected weight gain or reduce body fat deposition in a mammal. The breadth of the claims exacerbates the complex nature of the subject matter to which the present claims are directed.

The nature of the invention

Claims 1-2 are directed to a method of use of methyl pyruvate or methyl pyruvic acid to control the weight or to induce a weight loss or to reduce and expected weight gain or reduce body fat deposition in a mammal. Claims 3-4 are directed to a method of reducing body fat deposition in a mammal. Claims 5-17 and 20-28 are directed to the mode of administration, the form of administration, the amount administered, the form the methyl pyruvate compounds that are administered and the co-administration of a second compound.

The state of the prior art

The state of the prior art does not show the use methyl pyruvate or methyl pyruvic acid to control the weight or to induce a weight loss or to reduce and expected weight gain or reduce body fat deposition in a mammal. Prior art as disclosed by Stanko (US Patent 4, 548,937) teaches pyruvate is able to prevent body fat deposition, but make no mention of the methyl ester, methyl pyruvate or methyl pyruvic acid. Beale (US Patent 6,008, 252) teaches the administration of the esters of pyruvate are advantageous to increase the metabolism of fat in the body. Prior art as disclosed by Fang (US Patent 5,886,040) teaches a composition of methyl pyruvate with creatine to increase the palatability of the salt and further discloses the compound has the same physiological benefit of pyruvic acid.

Relative skill of those in the art

The relative skill of those in the art is high, generally that of a PhD with several years of practical experience.

The level of predictability in the art

The instant claimed invention is highly unpredictable. It has not been established in the prior art or by applicant that the administration of methyl pyruvate or methyl pyruvic acid, via sidestepping the first step in glycolysis, is able to control the weight or to induce a weight loss or to reduce an expected weight gain or reduce body fat deposition in a mammal. Due to the unpredictability in the pharmaceutical art, the invention is required to be assessed for physiological activity by *in vitro* and *in vivo* screening to determine which form of the methyl pyruvate compounds or methyl pyruvic acid compound exhibit the desired pharmacological activity. The lack of *any* guidance from the present specification or prior art with regard to the actual administration of *any* form of methyl pyruvate compounds or methyl pyruvic acid compound in a mammal with the intention of showing an administration route and dosage, showing that methyl pyruvate or methyl pyruvic acid levels and effects are increased in a mammal and that the methyl pyruvate compounds or pyruvic acid compound are capable of controlling the weight or to induce a weight loss or to reduce and expected weight gain or reduce body fat deposition in a mammal makes practicing the claimed invention unpredictable. Because Applicant failed to provide examples, scholarly discussion or prior art in support of weight loss, decreased fat deposition or control of weight, the Examiner

believes Applicant speculates that because of the structural similarities of methyl pyruvate to pyruvate (as disclosed in Stanko referenced above), methyl pyruvate will have the functionality of pyruvate.

Applicant is reminded of the decision *Genentech Inc. vs. NovaNordisk* which states, "[A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Circuit 1997).

The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. *In re Fisher, 427 F. 2d, 833, 166 USPQ 18 (CCPA 1970)*, indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, one of skill in the art is unable to fully predict possible results from the administration of the compound.

The amount of direction provided by the Applicant and The existence of working examples

The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and practice the claimed method commensurate in the scope with the instant claims. No examples exist for administering the pyruvate or methyl pyruvic acid *in vivo*. Without administering the compound to a mammal, one cannot predict if methyl pyruvate or methyl pyruvic acid

levels and effects are increased in the mammal or determine the administration route, dosages and frequency of dosing. With no results, it is difficult to envision that the compounds instantly claimed can control the weight or to induce a weight loss or to reduce and expected weight gain or reduces body fat deposition in a mammal.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation (*In re Wright, 999 F. 2d 1557, 1562; 27 USPQ 2d 1510, 1514 (Fed. Cir. 1993)*). The specification lacks sufficient disclosure to support applicant's claims of a method of controlling the weight or to induce a weight loss or to reduce and expected weight gain or reduce body fat deposition in a mammal by administration of any form of methyl pyruvate or methyl pyruvic acid. Sufficient support, working examples or data from references in the prior art providing a nexus between that which applicant asserts as efficacy of methods of controlling the weight or to induce a weight loss or to reduce and expected weight gain or reduce body fat deposition in a mammal and the amount of disclosure Applicant has actually provided, is absent.

The quantity of experimentation needed to make and use the invention based on the content of the disclosure

Based on the unpredictable nature of the invention, the state of the prior art and the breadth of the claims, one skilled in the art could not practice the claimed invention

without undue experimentation. The essential element towards the validation of a therapeutic modality capable of performing the mechanism of action is the ability to test the compound in cells *in vitro,* monitored in advance of administration of a compound, and link those results with subsequent histological results. Once it can be documented that that each of the compounds of interest elicits a desired pharmacological response, such as increased fat loss, the compounds could then be tested in an animal model.

With respect to the *in vivo* treatment of a mammal with the instant compounds to control the weight or to induce a weight loss or to reduce and expected weight gain or reduce body fat deposition in a mammal, absent a reasonable *a priori* expectation of success for using a specific drug regimen, one skilled in the art would have to test the drug regimen extensively. Since each prospective embodiment would have to be empirically tested, and those which initially failed tested further, an undue amount of experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not practice the claimed invention without undue experimentation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S Non- Provisional Application No.10/710710

25. Claims 1-2, 5-17 and 20-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-17 and 20-28 of copending Application No. 10/710710. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the independent claims (claims 1 and 2) of U.S Non- Provisional Application No.10/710710 and the independent claims in the instant application (claims 1 and 2) read on anyone to whom methyl pyruvate or methyl pyruvic acid is administered. For example, Application 10/710, 830 states in Claim 1, "We claim a method of controlling the weight or to induce a weight loss or to reduce an expected weight gain from a given diet in a mammal with the use of methyl pyruvate." and comparatively Application 10/710,710 states, "We claim a method of increasing muscle energy production, muscle respiration and performance in a mammal with the use of methyl pyruvate." As can be

seen in the compared claims, without an intended subject for which the compound is administered, the claims read on anyone. Following the independent claims 1 and 2, the remainder of the claims is verbatim for both applications. To exemplify, notice that claim 15 which states, "We claim the method of claim 13, in the form of lozenges, tablets, pills, capsules, powders, granulates, sachets, syrups or vials " is verbatim in both applications and has the same claim dependencies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

U.S Non- Provisional Application No.10/711255

26. Claims 1-2, 5-17 and 20-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 and 23-31 of copending Application No. 10/711255. Although the conflicting claims are not identical, they are not patentably distinct from each other because the independent claims (claims 1 and 2) of U.S Non- Provisional Application No.10/711255 and the independent claims in the instant application (claims 1 and 2) read on anyone to whom methyl pyruvate or methyl pyruvic acid is administered. For example, Application 10/710, 830 states in Claim 1, "We claim a method of controlling the weight or to induce a weight loss or to reduce an expected weight gain from a given diet in a mammal with the use of methyl pyruvate." and comparatively Application 10/711, 255 states, "We claim a method of increasing neuronal energy production with the use of methyl pyruvate in a human." As can be seen in the compared claims, without an intended

subject for which the compound is administered, the claims read on anyone. Following the independent claims 1 and 2, the remainder of the claims read on Application 10/710,830. To exemplify, notice that claim 15 which states, "We claim the method of claim 13, in the form of lozenges, tablets, pills, capsules, powders, granulates, sachets, syrups or vials." is verbatim in both applications and has the same claim dependencies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

U.S Non- Provisional Application No.10/904648

27. Claims 1-2, 5-15, 21, 23, 25 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, 20, 22, 24 and 26 of copending Application No.10/904648. Although the conflicting claims are not identical, they are not patentably distinct from each other because the independent claims (claims 1 and 2) of U.S Non- Provisional Application No. 10/904648 and the independent claims in the instant application (claims 1 and 2) read on anyone to whom methyl pyruvate or methyl pyruvic acid is administered. For example, Application 10/710, 830 states in Claim 1, "We claim a method of controlling the weight or to induce a weight loss or to reduce an expected weight gain from a given diet in a mammal with the use of methyl pyruvate " and comparatively Application 10/904, 648 states, "We claim a method of increasing cellular energy production with the use of methyl pyruvate in a human." As can be seen in the compared claims, without an intended subject for which the compound is administered, the claims read on anyone. Following the

independent claims 1 and 2, the remainder of the claims read on Application 10/710,830. To exemplify, notice that claim 15 which states, "We claim the method of claim 13, in the form of lozenges, tablets, pills, capsules, powders, granulates, sachets, syrups or vials." is verbatim in both applications and has the same claim dependencies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joseph Kosterlitz

JK

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PHYLLIS SPIVACK
PRIMARY EXAMINER 2/3/08